UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

ZHP DEFENDANTS' MEMORANDUM IN SUPPORT OF SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT[1]

[1] This Supplemental Motion for Summary Judgment concerns the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"), specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC ("MSP"), as class representative of TPP Breach of Express Warranty subclass b, TPP Breach of Implied Warranty subclass d, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a (collectively, the "TPP Classes"). (ECF 2343 at 1-2.) Accordingly, this motion is limited to the TPP Trial Claims, and is presented without waiver of any arguments for summary judgment with respect to any other claims asserted by any Plaintiff as to any Defendant in this multi-district litigation.

INTRODUCTION

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc. ("Huahai"), Prinston Pharmaceutical Inc. ("Prinston"), and Solco Healthcare U.S., LLC ("Solco") (collectively, the "ZHP Defendants") submit this separate summary judgment motion to address additional reasons why Plaintiffs' claims against the ZHP Defendants fail, in addition to all the reasons set forth in the TPP Trial Defendants' joint summary judgment motion ("Omnibus Motion").

First, Plaintiffs' claims against ZHP and Huahai are barred because there is no evidence that either entity manufactured or sold any finished-dose VCDs. Accordingly, neither company could have made any representations or warranties to the TPP class or their insureds that could give rise to express warranty, fraud or consumer protection claims.

Second, to the extent Plaintiffs' claims against Prinston and Solco are based on the allegation that the VCDs manufactured by Prinston d/b/a Solco were "adulterated" and therefore "worthless," those claims fail because the FDA has the sole authority to declare a medication adulterated and has never done so with respect to any VCD manufactured by these companies.

Third, Plaintiffs' fraud claims against the ZHP Defendants also fail because Plaintiffs lack evidence that the ZHP Defendants engaged in any knowing or intentional misrepresentations, as required under the applicable states' fraud laws.

FACTUAL BACKGROUND

The facts relevant to this motion are set forth in detail in Defendants' Omnibus Statement of Undisputed Material Facts ("SUMF"), which is incorporated herein, and are summarized briefly below.

Plaintiffs assert claims against four related entities referenced as "the ZHP Defendants": ZHP; Huahai, Prinston and Solco. (Third Am. Compl. ¶¶ 75-79, ECF 1708.) ZHP is the entity that manufactured and sold the active pharmaceutical ingredient ("API") used in certain recalled VCDs, but it did not market or sell any finished-dose VCDs and did not hold an Abbreviated New Drug Application ("ANDA") for any finished-dose VCD. (SUMF ¶ 3.) Further, ZHP did not make any warranties or representations prior to July 2018 regarding the presence or absence of NDMA in its valsartan API or any VCD. (*Id.* ¶ 83.) Huahai, a subsidiary of ZHP located in the United States, also did not market or sell finished-dose VCDs, did not hold an ANDA for any VCD, and did not make any warranties or representations prior to July 2018 regarding the presence or absence of NDMA in either VCDs or ZHP's valsartan API. (*Id.* ¶¶ 3 n.4, 81, 83.)

Solco is a subsidiary of Prinston, which is an indirect subsidiary of ZHP. Together, Prinston and Solco marketed and sold certain VCDs using ZHP's API that were included in the 2018 recall. (*Id.* ¶ 3.) Prinston held the ANDAs for these recalled VCDs, which were sold by Solco under the Solco label. (*Id.* ¶ 3 n.5.)

ARGUMENT

The summary judgment standard is set forth in the Omnibus Motion and incorporated herein.[2]

I. PLAINTIFFS' CLAIMS AGAINST ZHP AND HUAHAI FAIL BECAUSE THESE ENTITIES DID NOT MARKET OR SELL FINISHED-DOSE VCDS.

All of Plaintiffs' claims against ZHP and Huahai fail because neither company marketed or sold finished-dose products.

First, because they did not market or sell finished-dose medications, neither defendant could have made any express warranty to any TPP or consumer. As explained in the Omnibus Motion, Plaintiffs cannot establish the existence of ***any*** express warranty made by ***any*** of the Defendants to the Plaintiffs. (*See* Omnibus Motion at 16-18.) But even if Plaintiffs could establish that the labels, packaging or marketing of finished-dose VCDs constituted express warranties, such alleged warranties are not attributable to either ZHP or Huahai because these entities did not market or sell VCDs.

While most of the jurisdictions at issue in subclass b have relaxed the privity requirement for express warranty claims, they still require evidence that the

[2] As discussed in the Omnibus Motion (incorporated herein), it is impossible to determine what laws govern the claims of the TPP class members. Thus, as in the Omnibus Motion, the ZHP Defendants assume (contrary to law) that the claims at issue are governed by the 43 jurisdictions identified across the four subclasses set for trial.

defendant made an express warranty ***that was directed at the purchaser***. *See, e.g.*, *Holland v. Abbott Lab'ys, Inc.*, 626 F. Supp. 3d 1256, 1263 & n.5 (M.D. Fla. 2022) ("Florida law also requires privity for breach of express warranty claims" absent evidence that the "buyer has substantial communications directly with the manufacturer or where a manufacturer has heavy involvement with a transaction between the buyer and third-party distributor"); *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 743-44 (D.N.J. 2021) ("Georgia law still generally precludes the ultimate consumer from recovering on any express or implied warranty when the manufacturer sells the product to the original consumer, e.g. a retailer" absent evidence that "the manufacturer expressly warrants to the ultimate consumer that the product will perform in a certain way or that it meets particular standards") (citation omitted). Here, Plaintiffs have no evidence that ZHP or Huahai directly marketed valsartan API to TPPs, much less that these companies made any warranties or representations to TPPs regarding the presence or absence of NDMA in ZHP's valsartan API prior to July 2018. (*See* SUMF ¶ 83.) Accordingly, Plaintiffs' express warranty claims fail for this reason too.

Second, Plaintiffs' fraud and consumer-protection claims against ZHP and Huahai fail for similar reasons. While there are material "variations among state consumer protection acts" and common-law fraud regimes with regard to the type

of conduct that is actionable, these varying standards require, at a minimum, evidence of a false or deceptive statement or omission. (*See* Omnibus Motion, Section I.B.1.) Here, Plaintiffs have no evidence that either ZHP and Huahai made ***any*** representations to the TPP class or consumers regarding VCDs ***or*** ZHP's valsartan API prior to July 2018. Thus, Plaintiffs' fraud-based claims also fail.

Third, Plaintiffs' implied warranty claims against ZHP and Huahai fail for lack of privity. As explained in the Omnibus Motion, Plaintiffs cannot establish that they are in privity of contract with any of the TPP Trial Defendants. (Omnibus Motion, Section I.A.2.) Lack of privity is fatal to Plaintiffs' implied warranty claims because, as the Court acknowledged in its class certification order, privity is a requirement for implied warranty claims in all seven jurisdictions included in the subclass set for trial (i.e., Alabama, New York, Ohio, Oregon, Tennessee, Utah and Vermont). (*See* ECF 2261 at 40, 45; Omnibus Motion, Section I.A.2.)

Even if the Court were to determine that there is evidence of privity with respect to certain TPP Trial Defendants (and there is none), it is without question lacking with respect to ZHP and Huahai. ZHP is neither the ANDA holder nor the seller of the product allegedly covered by the Plaintiffs under prescription drug plans. And Huahai is a subsidiary of ZHP that played no role in the marketing or selling any VCD at issue. As a result, Plaintiffs have no evidence of a direct contractual relationship between ZHP or Huahai and any Plaintiff. (SUMF ¶¶ 3 &

n.4, 107.) Accordingly, ZHP and Huahai are entitled to summary judgment on this claim too.

II. PLAINTIFFS CANNOT PROVE THAT ANY FINISHED-DOSE VCD SOLD BY PRINSTON D/B/A SOLCO WAS ADULTERATED OR MISBRANDED.

All of Plaintiffs' claims against the ZHP Defendants fail because none of the finished dose VCDs marketed and sold by Prinston d/b/a Solco have been deemed adulterated or misbranded by the FDA.

Plaintiffs' entire theory of damages is grounded in a theory that the recalled VCDs "were adulterated and misbranded" and, thus, could not be sold in the United States, rendering them worthless. (Damages Decl. of Rena Conti ¶¶ 2, 4, Nov. 10, 2021 (SUMF Ex. 6); *see also id.* ¶ 46 (opining that "non-complaint, adulterated and misbranded prescription drugs have no economic value").) But "adulteration" and "misbranding" are regulatory classifications that are imposed solely by the FDA; they are not issues of fact for a jury to decide de novo. *See* 21 U.S.C. § 351; *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001) (refusing to grant injunctive relief based on allegations of adulteration because "[c]laims of adulteration ***should be resolved by the FDA***") (emphasis added).

Because the FDA has never made any statement or determination that finished-dose VCDs marketed and sold by Prinston d/b/a Solco were adulterated or misbranded, all of Plaintiffs' claims against the ZHP Defendants fail as a matter of

law and summary judgment is appropriate.

III. PLAINTIFFS LACK SUFFICIENT EVIDENCE TO PROVE SCIENTER AS TO ANY OF THE ZHP DEFENDANTS.

Finally, in addition to all the reasons set forth in the Omnibus Motion, Plaintiffs' common-law fraud claims also fail for lack of scienter, which is required in the subclass states. (*See* ECF 2261 at 32; ECF 2261-3 at H-3, H-13, H-18 to H-19, H-22, H-29, H-31, H-33, H-40 to H-54.)[3] *See In re TMJ Implants Prods. Liab. Litig.*, 880 F. Supp. 1311, 1317 (D. Minn. 1995) (granting summary judgment on fraudulent misrepresentation and omission claims regarding safety of silicone breast implants because plaintiff offered no evidence of defendant's knowledge of the danger), *aff'd*, 113 F.3d 1484 (8th Cir. 1997).

The undisputed evidence shows that prior to making the manufacturing changes that led to the impurities, ZHP ran a number of tests on the possible effects from its changes, and none indicated that these impurities would form. (*See* SUMF ¶ 10 (citing SUMF Ex. 16, ZHP01838512 at 517 (certified translation at 4) (noting that "[a]dding sodium nitrite quenching operation can effectively remove azide ions in the reaction solution, and basically will not cause negative effects on product

[3] Several of the jurisdictions at issue (Iowa, Louisiana, North Carolina, Ohio, South Dakota, Virginia and Washington, D.C.) require even greater culpability—specifically, an intent to deceive or mislead beyond mere knowledge. (*See* ECF 2261 at 32; ECF 2261-3 at H-3, H-13, H-18 to H-19, H-22, H-29, H-31, H-33, H-40 to H-54.)

quality").) Statements from the FDA confirm that the formation of NDMA and NDEA was not reasonably foreseeable prior to 2018.[4]

Neither of Plaintiffs' two designated chemistry experts, Dr. Hecht or Dr. Najafi, identified any scientific literature reporting the formation of alleged NDMA or NDEA impurities in which valsartan API was manufactured during the relevant time period either. Regarding NDEA, Dr. Najafi conceded that he did not even know it was possible for ZHP's manufacturing processes to create NDEA until beginning his work on this litigation. (*See* SUMF ¶ 59.) And Plaintiffs' other expert, Dr. Hecht, admitted that nitrosation of a tertiary amine like TEA is extremely rare. (*See id.*)

The same is true for NDMA. Relying on a single Australian textbook, both of these experts assert that ZHP's use of a new solvent, DMF, should have raised concerns it could decompose into DMA at its boiling point, leading to the formation of small amounts of NDMA. (*See* SUMF ¶ 57.) But both experts conceded that ZHP's manufacturing processes never reached boiling temperature (*see id.* ¶ 58),

[4] For instance, in July 2018, the FDA stated that "the presence of NDMA was unexpected," and the FDA Commissioner reiterated just a month later that "[b]efore [the FDA] undertook [an] analysis, neither regulators nor industry fully understood how NDMA could form" during ZHP's manufacturing process. (*See* SUMF ¶¶ 61-62.) This is critical because, as the FDA has explained, "it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for." (*Id.* ¶¶ 64-65 (quoting FDA Statement, Jan. 25, 2019 "FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues" at 3 (SUMF Ex. 65)).)

and in any event, there is no evidence that anyone at any Defendant read any part of the isolated textbook. Dr. Najafi was not aware of this textbook until his retention for this litigation, while Dr. Hecht does not know if the isolated statements regarding DMF decomposition are common knowledge even today. (*See id.* ¶ 59.)

Although Dr. Najafi asserts that a 2017 email from ZHP employee Jinsheng Lin shows that ZHP did have knowledge of the potential for NDMA or NDEA resulting from its manufacturing processes (*see* SUMF ¶ 66), that email is not even about valsartan API—the product in question. Rather, Mr. Lin's email addresses a hypothetical nitrosated impurity in the lab-scale trial of Irbesartan, a different drug molecule than valsartan API. (*Id.*) Thus, the email does not establish, or even suggest, that ZHP had knowledge of the potential for NDMA or NDEA in valsartan prior to the 2018 events leading to the recall. In any event, "one internal email" cannot suffice to establish a triable question that ZHP (much less any of the other Defendants) knowingly misrepresented or failed to disclose material safety information. *See Tershakovec v. Ford Motor Co.*, 546 F. Supp. 3d 1348, 1364-65 (S.D. Fla. 2021) (granting summary judgment on omission-based fraud claims for lack of scienter where alleged knowledge was premised on one internal email), *aff'd in part, vacated in part, rev'd in part*, 79 F.4th 1299 (11th Cir. 2023).

Further, even if a single email involving a different medication and process could raise a question of fact as to scienter, it would only be relevant to ZHP's

knowledge as of July 2017, when the email was sent. As a result, Plaintiffs' fraud claims, and alleged damages, would be limited to VCD purchases in the short period between July 2017 and the recall of VCDs in July 2018.

CONCLUSION

For the foregoing reasons, the Court should grant the ZHP Defendants summary judgment.

Dated: December 22, 2023

Respectfully submitted,

By: */s/ Jessica Davidson*

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
Jessica Davidson (NY Bar No. 6034748)
Allison M. Brown (NJ Bar No. 044992012)
One Manhattan West
New York, New York 10001
Phone: (212) 735-3222
Fax: (917) 777-3222
jessica.davidson@skadden.com
allison.brown@skadden.com

Nina R. Rose (DC Bar No. 975927)
1440 New York Avenue, N.W.
Washington, D.C. 20005
Phone: (202) 371-7000
Fax: (202) 661-0525
nina.rose@skadden.com

Attorneys for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 22, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
Jessica Davidson
Skadden, Arps, Slate,
Meagher & Flom LLP